DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin and Praziquantel Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The NADA provides for use of a moxidectin and praziquantel oral gel for the treatment and control of various species of internal parasites in horses and ponies.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301–827–7543; e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141–216 for QUEST PLUS (moxidectin 2.0%/praziquantel 12.5%) Gel for the treatment and control of various species of internal parasites in horses and ponies. The NADA is approved as of May 14, 2003, and part 520 (21 CFR part 520) is amended by adding new § 520.1453 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and

NADA 141-216

NAR

information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520–ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1453 is added to read as follows:

§ 520.1453 Moxidectin and praziquantel gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (mg) (2.0 percent) moxidectin and 125 mg (12.5 percent) praziquantel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* Administer by mouth as a single dose: 0.4 mg moxidectin per kilogram and 2.5 mg praziquantel per kilogram (2.2 pounds) body weight.

(2) *Indications for use.* For treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adults and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cyathostomum catinatum* (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae)); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)); hairworms (*Trichostrongylus axei* (adults)); large-mouth stomach worms (*Habronema muscae* (adults)); horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)); and tapeworms (*Anoplocephala perfoliata* (adults)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

Dated: 8/13/03
August 13, 2003.

cv0314

Stephen F. Sundlof,
Director,
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